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MAP 17

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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
| 08/182,183 | 05/23/94 | LIN | BYUREK 7-24-11 |

18M2/0314

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EXAMINER
ALLEN, M

ART UNIT
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PAPER NUMBER

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03/14/97

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3 mos sleep
6/14/97
6 mos
sleep
9/14/97*

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

| | |
|--------------------------------------|-----------------------------------|
| Application No. 08/182,183 | Applicant(s) Lin et al. |
| Examiner Marianne P. Allen | Group Art Unit 1818 |

 Responsive to communication(s) filed on Dec 30, 1996 This action is **FINAL**. Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims Claim(s) 26, 28, 29, 31, 34, 42-55, 75-86, and 88-116 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

 Claim(s) 88-94 is/are allowed. Claim(s) 26, 29, 31, 42-55, 75-86, and 95-116 is/are rejected. Claim(s) 28 and 34 is/are objected to. Claims _____ are subject to restriction or election requirement.**Application Papers** See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948. The drawing(s) filed on _____ is/are objected to by the Examiner. The proposed drawing correction, filed on _____ is approved disapproved. The specification is objected to by the Examiner. The oath or declaration is objected to by the Examiner.**Priority under 35 U.S.C. § 119** Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All Some* None of the CERTIFIED copies of the priority documents have been

received.

received in Application No. (Series Code/Serial Number) _____.

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

 Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).**Attachment(s)** Notice of References Cited, PTO-892 Information Disclosure Statement(s), PTO-1449, Paper No(s). _____ Interview Summary, PTO-413 Notice of Draftsperson's Patent Drawing Review, PTO-948 Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

Claim 87 has been cancelled. Claims 95-116 have been newly added. Claims 26, 28-29, 31, 34, 42-55, 75-86, 88-94, and 95-116 are under consideration by the Examiner. ✓

5 Applicant states that they have included all pending claims in the first submission after final rejection. Applicant is requested not to do this because it creates confusion regarding claims that need to be entered as well as introduces errors. For example, claim 44 is incorrect. Applicant is directed to the previous amendment of this claim which recites --cloning-- instead of "subcloning" in part (a) and deletes "amplification of the vector and" in part (c). It is unclear if claim 86 in this submission was intended to be an amendment to be entered. Claim 86 as it presently stands includes the recitation of --prokaryotic and eukaryotic-- in part (a). This does not correspond to what is listed in the present response. Claim 86 in the present response has not been treated as an amendment. ✓

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15 The disclosure is objected to because of the following informalities: Claim 114 lacks a terminal period ("."). ✓

Appropriate correction is required.

20 Claims 26, 29, 31, 42-55, 75-86, 95-106, 108-115 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

25 The claims have been amended to recite "at least 70% identical" and "at least 90% identical" However, the specification at page 13 discloses in excess of (that is, greater than) 70% and 90%.

No basis has been established for 70% itself.

Should this portion of the rejection be overcome, applicant is advised that the material incorporated by reference to Dayhoff et al. is deemed to be essential material to enable the claims in view of the new limitations regarding alignment. This material is improperly incorporated by reference.

The incorporation of essential material by reference to a publication inserted in the specification is improper. Applicant is required to amend the disclosure to include the material incorporated by reference. The amendment must be accompanied by an affidavit or declaration executed by the applicant, or a practitioner representing the applicant, stating that the amendatory material consists of the same material incorporated by reference in the referencing application. *In re Hawkins*, 486 F.2d 569, 179 USPQ 157 (CCPA 1973); *In re Hawkins*, 486 F.2d 579, 179 USPQ 163 (CCPA 1973); *In re Hawkins*, 486 F.2d 577, 179 USPQ 167 (CCPA 1973).

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Claim 26 has also been amended to recite "under conditions of reduced stringency." The portion of the specification pointed to do not provide basis for this limitation. That is, particular conditions used in Example 2 on page 63 do not provide basis for the generic concept of reduced stringency.

The basis for claim 29 is not clear. It is not apparent from the specification where basis for adding nucleotides encoding the pre-pro amino acid sequence to hybridizing sequences and those having 70 % identity is found. (See parts (c) and (d) of claim 26.)

The basis for claims 110 and 112 is not clear. It is not apparent from the specification where basis for refolding a glycosylated dimer or secretion of a dimer is found. With respect to claim 110, the specification discloses refolding of monomers produced in E. coli; however, these would not be glycosylated.

No basis has been pointed out for the subject matter of claim 113 and none is apparent.

With respect to claim 50, the specification does not appear to describe what "conditions for amplification of the vector" encompass or what types of amplification are intended. "Amplification" to one of ordinary skill in the art could include such diverse processes as PCR amplification and methotrexate amplification. It is noted that claim 44 was previously amended to remove this limitation.

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Claims 95-98 and 101 as written encompass production of the glial cell line-derived neurotrophic factor by a transgenic animal. The specification does not appear to describe nor enable production or isolation thereof and it would constitute undue experimentation to practice the invention as claimed. Transgenic techniques would not have been predictable for production of a heterologous protein at the time of the invention. It appears that if this claim were put in a form similar to that of claims 50, 86, or 94, the scope of claim 95 would be essentially that of claim 50 which ultimately depends upon claim 26.

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Likewise, claims 108-112 as written encompass production of the glial cell line-derived neurotrophic factor by a transgenic animal which is not described nor enabled as set forth above. Furthermore, the single step of "modifying a cell to express" does not appear to be sufficient to make the claim complete. That is, there is no step requiring that the neurotrophic factor is in fact expressed such as culturing the cell under appropriate conditions.

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Claim 116 is rejected under 35 U.S.C. 112, first paragraph, because the specification does not reasonably provide enablement for all glial cell line-derived neurotrophic factor nucleic acid sequences. The specification does not enable any person skilled in the art to which it pertains, or with

which it is most nearly connected, to make and use the invention commensurate in scope with this claims.

The specification does not describe nor enable identification of any other nucleic acid sequences encoding a GDNF protein meeting the limitations set forth in claim 116 other than those that are variants derived from the specifically identified sequences. The enablement of the claims can be viewed similarly to those in Ex parte Maizel, 27 USPQ2d 1662, 1665, as set forth in the prior Office actions. The claims encompass completely unrelated nucleic acid molecules that encode equivalent proteins. The disclosure is not commensurate in scope with the breadth of this claim.

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Claim 107 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claim 107 recites "host cell transformed or transfected to express a polypeptide." It is unclear what applicant is claiming. Is the claim directed to a host cell transformed or transfected with a nucleic acid sequence encoding the polypeptide of SEQ ID NO: 4 or SEQ ID NO: 6? Is the claim directed to a host cell transformed or transfected with an expression vector comprising the nucleic acid sequence encoding the polypeptide of SEQ ID NO: 4 or SEQ ID NO: 6? Or is something else intended?

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It is believed that all pertinent arguments have been addressed.

IF NEEDED IN
NEXT P, ARGUE
GENE ACTIVATION
U.S. 5,272,071

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marianne P. Allen, whose telephone number is (703) 308-0666. The examiner can normally be reached on Monday-Friday from 7:30 am to 4:00 pm.

5 If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Donald E. Adams, Ph.D., can be reached on (703) 308-0570. The most convenient FAX telephone number for this examiner is (703) 308-0294.

10 Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Marianne P. Allen
MARIANNE P. ALLEN
PRIMARY EXAMINER
GROUP 1800